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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,831	02/16/2001	Mikael Forsberg	10806-60A	3598

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EXAMINER

SIPOS, JOHN

ART UNIT	PAPER NUMBER
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3721

DATE MAILED: 07/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/785,831

Applicant(s)

FORSBERG ET AL.

Examiner

John Sipos

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28,79 and 97-102 is/are pending in the application.
- 4a) Of the above claim(s) 1-20,79 and 97-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: \_\_\_\_\_

### ***ELECTION***

Applicant's election of claims 21-27 and 79 in Paper No. 7 is acknowledged.

### ***RESTRICTION REQUIREMENT***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

**Group I. Claims 21-27**, drawn to a method of making and filling an ampoule, classified in Class 53, subclass 462.

**Group II. Claim 79**, drawn to a method of manufacturing prefilled ampoules in a carrier tray, classified in Class 53, subclass 467.

The inventions are distinct, each from the other, because of the following reasons:

The inventions of Groups I and II are related as **subcombinations disclosed as useable together in a single combination**. The subcombinations are distinct from each other if they are shown to be separately useable. In the instant case, the invention of Group I has separate utility because it can be used to make and fill individual ampoules without resorting to the method of using a carrier/tray (See MPEP 806.05(d)).

Because these inventions are distinct for the reasons given above, and because they have acquired a separate status in the art as shown by their different classifications, restriction for examination purposes, as indicated, is proper.

Applicant is advised that the response to this requirement, to be complete, must include an election of the invention to be examined even if the restriction requirement is traversed.

During a telephone conversation between Examiner John Sipos and Mr. S. S. Wenstler, attorney of record in this case, on July 23, 2002, a provisional election was made with traverse to prosecute the invention of Group I comprising claims 21-27. Affirmation of this election must be made by applicant in responding to this Office action. Claim 79 is withdrawn from further consideration by the examiner as being drawn to a non-elected invention. (See 37 CFR 1.142(b)). An action on the merits of the elected claims follows.

Applicant is reminded that, upon cancellation of claims to a non-elected invention, the **inventorship must be amended** in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h). Applicant should further **amend the title**, in necessary, to reflect the elected invention.

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***OBJECTION TO THE SPECIFICATION***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction

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of the following is required: The claims set forth the insertion of the piston into the front chamber through the front opening of the barrel. However, the specification does not specifically set forth whether the insertion takes place through the front or the rear opening.

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***REJECTION ON PRIOR ART***

The following is a quotation of 35 U.S.C. ' 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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**Claims 21-27** are rejected under **35 U.S.C. ' 103(a)** as being unpatentable over the patent to Hjertman (5,435,076). The patent to Hjertman discloses the method of forming an ampoule by inserting a first piston 3 into the front chamber 5 of the barrel, filling the front chamber with a solution, performing a lyophilizing step, sealing the front opening of the barrel by inserting a sealer 11 into the opening, connecting and securing the sealer with the sleeve 7 at 10, 12, filling the second chamber with material 6 and inserting a second piston 25 into the barrel. The patent does not disclose how the first piston is inserted into the barrel. Since the barrel is empty at the time of insertion of the first piston and since applicant has not disclosed that the use of either opening provides an advantage, is used for a particular purpose, or solves a stated problem, it would

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have been obvious to one of ordinary skilled in the art to insert the piston through either the front or rear opening.


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Any inquiry concerning this communication should be directed to **Examiner John Sipos** at telephone number **(703) 308-1882**. The examiner can normally be reached from 6:30 AM to 4:00 PM Monday through Thursday.

The **FAX** number for Group 3700 of the Patent and Trademark Office is **(703) 872-9302**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Rinaldi Rada, can be reached at (703) 308-2187.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist whose telephone number is (703) 308-1148.

  
**John Sipos**  
**Primary Examiner**  
**Art Unit 3721**

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